PROPOSED TOPIC FOR STUDY BY STUDENTS

EPA TRANSPARENCY RULE

A. Alan Moghissi

Given the enormous disagreement on the proposed rule *Strengthening Transparency in Regulatory Science*, it is desirable to perform a study addressing the issue based on fundamentals of regulatory science. In 2011, I testified before the Subcommittee on Energy and Environment of the Committee on Science, Space and Technology of the House of Representative and asked for the passage of *Regulatory Science Sunshine Act.*

The publication of proposed regulation of the Environmental Protection Agency (EPA 2018) resulted in over 500,000 comments including about 9,000 specific comments. A cursory evaluation of the comments identified three specific groups

Group 1: The proponents of the EPA proposal claim that EPA is correct in implying that unless the underlying data are publicly available, no scientific information may be used in the development of regulations.

Group 2: The opponents of the EPA proposal claim that requirements of transparency would eliminate key studies notably Six-Cities and the American Cancer Society (ACS) studies that were used previously by the EPA to regulated certain pollutants notably particulate matter (PM).

Group 3: This group can be designated as regulatory scientists. Based on the criteria identified in our paper (Moghissi et al 2018) both groups are partially right.

The Ethical Rules Principle of Best Available Regulatory Science (BARS) includes communicability and transparency as advocated by the first group. Pillar of Metrics for Evaluation of Regulatory Science Claims (MERSC) derived from BARS consist of Standardization (establishment of level of maturity) of science, Reliability of science, and Areas Outside the Purview of Science. Consequently Group 1 is correct

There are limitations on implementing transparency. Many data and other information may not be released including national security, privacy, specific business data, and others that their release would be harmful. Consequently Group 2 is correct.

The solution is to develop a process that maintains the concerns of Group2 and ensures the transparency requirements. As described by Moghissi et al (in press), one of the key issues identified in Group 2, was two key epidemiological studies used by the EPA in the regulatory process consisting of Six Cities study, and American Cancer Society (ACS) study. The Six Cities study claim that they cannot publicly release the data as the rule of the privacy would be violated. The need for transparency demonstrated by the evaluation of both studies by a group

who agreed with their conclusions. In contrast the ACS study was evaluated by another group who came to opposite conclusion

The true solution is to develop a process that makes the data identified by Group2 available for reevaluation without violating ethical principles. For the sake of simplicity, this process is referred to as ***Protected Transparency*** or ***Controlled Transparency***. For example, many universities, research organizations and other groups have a process that uses personal data for research and assessment, but like the authors of Six Cities and ACS studies, the process protects personal information. These organizations use processes such as Institutional Review Board (IRB) that reviews all relevant studies and ensures compliance with privacy requirement including ethical, legal, and any other relevant issue.

References

Moghissi AA. The need for regulatory science transparency at the EPA. Testimony before the Subcommittee on Energy and Environment; Committee on Science, Space, and Technology; House of Representatives. November 30, 2011

Environmental Protection Agency. Strengthening transparency in regulatory science. *Federal Register* 2018; 83 (No 83): 18768-18774

Moghissi AA, Calderone RA, Bambarger M, Estupigan C, Koch R, Manfredi K, and Vanderdys V. Innovation in Regulatory Science: Requirements for transparency and communicability of regulatory science. *Dose Response* (in Press)